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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PETERS, VERNY, JONES & BIKSA, LLP
Suite 6
385 Sherman Avenue
Palo Alto, CA 94306

EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,770	FERRARA ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *4-10,12,13,17,26-28,33,38,39 and 41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,11,14-16,18-25,29-32,34-37 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/8/03, 1/14/02*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Applicant's election with traverse of Invention I, claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 in the paper filed 12/29/2003 is acknowledged. The traversal is on the ground(s) that the groups of inventions are all part of the same invention. This is not found persuasive because the inventions are distinct as noted in the last Office Action, as shown by the distinctness described therein. Applicant's attention is directed to MPEP 806.05.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The amendment filed 8/14/2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants have amended the continuing information in the specification at page 1, paragraph 1. While that in and of itself is not new matter, the addition of the phrase "all of which are incorporated herein by reference in their entirety" constitutes new matter, as such incorporation by reference to applications 08/473276, 158027 and 360235 was not made in the specification as originally filed. The Examiner's position is supported by the decision in *In re Seversky*, 177 USPQ 144, in which it was found that a statement that an application is a continuation in part does not incorporate the contents of the parent application. The later application must itself contain the necessary disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claims 14, 18, 29, 30, and 34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each claim is drawn to a composition,

whereas the claims from which they depend are drawn to methods. A composition does not further limit a method.

Applicant is advised that should claims 1, and 15 be found allowable, claims 21 and 36, respectively, will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 40 is objected to because of the following informalities: in line 2 of the claim, "Claims" should read "claim". Appropriate correction is required.

Claim Interpretation

The presently claimed "Folliculo stellate-derived growth factor" is commonly known in the art as Vascular Endothelial cell Growth Factor, or VEGF. Other names for the same protein are vascular permeability factor (VPF), and glioma-derived vascular endothelial cell mitogen.

It is noted that those claims that are limited by sequence appear to be limited to bovine VEGF; confirmation is requested.

Claims 14, 18, 19, 29, 30 and 34 are product-by-process type claims. The purification or production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a protein is novel and unobvious over the prior art, the protein per se, even when limited to the particular process, is unpatentable over the same protein taught by the prior art. See In re King, 107 F.2d 618, 620, 43 U.S.P.Q. 400, 402 (C.C.P.A. 1939); In re Merz, 97 F.2d 599, 601, 38 U.S.P.Q. 143, 144-45 (C.C.P.A. 1938); In re Bergy, 563 F.2d 1031, 1035, 195 U.S.P.Q. 344, 348 (C.C.P.A. 1977) vacated 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 U.S.P.Q. 529, 543 (D.N.J. 1979). As none of the recited processes would

result in a particular degree of purity, nor affect the composition of the resultant protein, such limitations are given only minimal weight.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 14, 18, 21, 29, 30, and 34, are indefinite because the mere recitation of a name, i.e. Folliculo stellate-derived growth factor, to describe the claimed invention is not sufficient to satisfy the statutes requirement of adequately describing and setting forth the inventive concept. In order to avoid possible confusion over proteins with the same or similar names that may be found to have patentably different structure and/or utility, proteins claimed by a particular name should be further distinguished in the claims by conventional protein characterization according to known parameters, e.g. such as by molecular weight, pI, amino acid sequence information, whether the protein is a monomer or multimeric, function(s) and/or activity, and/or other finger-printing techniques such as IR, NMR, or UV spectroscopy data and/or other known properties which would serve to distinguish the claimed protein from other proteins. In addition, in consideration of the discrepancies often encountered in the art between protein molecular weights when determined by different methods, whenever a molecular weight is recited to characterize a protein the claim should include the method by which it was determined, e.g. whether by sodium docecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, and whether reducing or non-reducing (native) conditions were used.

For reasons cited above, claims which recite molecular weights without reference to how such are measured, for example claims 22 and 36, are indefinite.

Claims 2 and 23 are indefinite for reciting "SS polyacrylamide electrophoresis". Such is not a recognized term in the art, nor is such found in the specification. Amendment to read "SDS" rather than "SS" would be remedial.

Claim 30 is an improper composition claim. A composition must comprise at least two elements.

Claim 32 is indefinite as there is no antecedent basis in claim 21 for a pharmaceutical composition.

Claim 40 is indefinite as it states that "the amino acids in parenthesis are certain", which puts into question the certainty of the un-parenthesized amino acids.

The remaining claims are rejected for depending on an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 20 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims require the recombinant DNA production of the claimed protein. That would entail having the DNA encoding said protein, and expressing such in an appropriate host cell system. Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Simply put, the claims require a full-length, functional nucleic acid sequence encoding folliculo-stellate derived growth factor, whereas the specification provides only a very small portion of the amino acid sequence of the bovine protein, and does not provide any nucleic acid sequence from any species. The specification merely provides an invitation to find the nucleic acid, and does not provide any evidence of possession of such nucleic acids. The skilled artisan cannot envision the detailed chemical structure of the polynucleotides required for the process recited in the rejected claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In this case only a partial amino acid sequence is provided. No complete amino acid sequence is provided, and no nucleic acids are provided.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 19, 20 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejected claims are product-by-process claims, to protein which has been produced by recombinant DNA methodology. The specification at page 39 presents a proposed method for cloning such DNA, based upon the use of unspecified probes based on the amino acid sequence of bovine FsdGF. This is insufficient to enable the recombinant production of FsdGF because (a) no particular probe is disclosed, thus it was unpredictable whether the extremely limited amount of information as to the bovine sequence which is provided in the specification as filed would provide the requisite information so as to allow such cloning without undue

experimentation. Simply put, the claims require a full-length, functional nucleic acid sequence, whereas the specification provides only a very small portion of the amino acid sequence of the bovine protein, and does not provide any nucleic acid sequence from any species. The specification merely provides an invitation to find the nucleic acid, and does not provide sufficient information so as to allow the person of ordinary skill in the art to obtain such predictably or without undue experimentation. Without possession of the nucleic acid sequence, one could not obtain the protein as it is claimed in claims 19, 20 and 40. The specification proposes that the skilled artisan use synthetic oligonucleotide probes to screen a bovine cDNA or genomic DNA library for VEGF and then use the resultant bovine cDNA to screen for a human cDNA for VEGF. This is insufficient to enable the claims because one cannot make that of which one has no conception. First, a partial amino acid sequence, and a synthetic oligonucleotide sequence derived from it, puts no limitations upon the amino acid or nucleotide sequence of the full sequence. Thus, since the VEGF monomer is approximately 23 kDal, which consists roughly of 200 amino acids, the coding sequence of the DNA would have to include at least 600 bp, and, since the partial sequence places no restriction on the sequence to which it is attached, there are approximately 10^{11} different possible nucleotide sequences (600^4) for the coding region alone. The specification provides no working examples of any VEGF DNA, and, since the complete amino acid sequence is not known, no guidance as to how one would predict what a VEGF DNA would look like. Second, from a practical point of view, screening a library with a synthetic oligonucleotide can produce many false positives. There are numerous pseudogenes that have regions that resemble the DNA encoding functional proteins. However, in the case where only a limited amount of sequence for the protein is known, how could the skilled artisan determine whether the DNA molecule isolated using the oligonucleotide probe will encode VEGF, encode another protein, or whether the DNA is just genetic junk? Presumably, the skilled artisan would have to clone the entire DNA molecule, express it recombinantly, and then determine if it has the same activity as that of isolated VEGF. In the absence of any working examples, any guidance as to the structure of the claimed nucleic acids, and the unpredictability inherent in making nucleic acids to encode proteins which are defined almost solely by function, it would require undue experimentation to practice the claimed invention. Therefore, the specification as filed does not teach how to make the product as it is

claimed in claims 19, 20 and 40. It was found in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 at 1017 that conception may not be achieved until reduction to practice in cases involving cloning genes. In the instant case, there is no conception of the recombinant production of the claimed protein in the absence of a conception of the DNA necessary for such recombinant production, and there is no conception of that DNA. Therefore, the claims are not enabled.

Claims 1, 11, 14-16, 18, 20-23, 25, 29-32, and 34-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on folliculo-stellate derived growth factor from any source. The specification describes the protein only as isolated from human and bovine sources.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the human and bovine proteins referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Although those cases related to the isolation of nucleic acids, the point is relevant here; although it would be reasonably predictable that other animal species would have homologous proteins, applicants have not evidenced either conception of such proteins, nor that they were in possession of such.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine

sequence. In this case the specification provides the bovine and human proteins and partial descriptions of each, but seeks cover for any and all proteins that might be termed "Folliculo stellate-derived growth factor", regardless of source.

Therefore, only human and bovine folliculo stellate-derived growth factors, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections under 35 U.S.C. §§102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1, 11, 14-16, 19-23, 25, 29-32 and 34-37 are rejected under 35 U.S.C. § 102(e) as being anticipated by Connelly et al. (U.S. Pat. No. 5,008,196, cited by applicants). The claims are drawn to a growth factor, isolated from guinea pig cells, which is a disulfide linked dimer which is approximately 43 kDal on non-reduced SDS PAGE, which stimulates endothelial cell proliferation and is effective in would healing between 10-500 pg/ml. Connolly et al. teaches purification and characterization of an endothelial cell growth factor (col. 2,line 1 to col. 3, line 55), which is effective in would healing at 10pg/ml (half-maximal - see column 9, lines 57-61). Claims 14 and 18-20 recite FSdGF made by recombinant techniques and claims 29-30 and 34-

35 recite FSdGF isolated via protein purification. Since the invention defined in a product-by-process claim is a product, not a process, then it is patentability of the product claimed and NOT of the recited process steps which must be established. Since the growth factor taught by Connolly reasonably appears to be the same as that of the instant application in terms of its molecular weight and activity even though it is derived from a different tissue source, the growth factor taught by Connolly appears to anticipate the protein of the instant application, absent evidence to the contrary.

Claims 1, 11, 14-16, 18-23, 25, 29-32 and 34-37 are rejected under 35 U.S.C. 102(b) as anticipated by Senger (Science, 219, 983-985, 1983, cited by applicants) and Dvorak (U.S. Pat. No. 4,456,550, cited by applicants). The reference teaches a vascular permeability growth factor (VPF) of about between 34-45 kD (non-reduced) (Senger, p. 983; Dvorak, col. 2, line 16 to col. 3, line 22). The factor was isolated from guinea pig, hamster, rat and mouse (see claims). It is known that FSdGF is the same protein as VEGF, which is the same as VPF. In addition, what is claimed is not protein only derived from folliculo-stellate cells, as the specification states that the term FSdGF and VEGF are intended to encompass the protein regardless of its source or manner of production (p. 10, lines 16-19).

Claims 1, 11, 14-16, 18-23, 25, 29-32 and 34-37 are rejected under 35 U.S.C. 102(a) as anticipated by Criscuolo et al (J. Neurosurg. 69, 254-262, 1988, cited by applicants). The reference teaches a human vascular permeability growth factor (VPF) of about between 41-56 kD (non-reduced) (see abstract) and compositions thereof. It is known that FSdGF is the same protein as VEGF, which is the same as VPF. In addition, what is claimed is not protein only derived from folliculo-stellate cells, as the specification states that the term FSdGF and VEGF are intended to encompass the protein regardless of its source or manner of production (p. 10, lines 16-19). The reference does not disclose the amino acid sequence, however in view of the similar activity and molecular weight, the VPF disclosed by Criscuolo reasonably appear to be the same as the protein of the instant application, absent evidence to the contrary. Since the species appear to be identical, the distinguishing features, such as the amino acid sequence,

would be inherently present in the species disclosed by the reference even though this feature is not specifically taught.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 are rejected under 35 U.S.C. § 103 as being unpatentable over Connolly et al. (U.S. Pat. No. 5,008,196, cited by applicants) or Senger (Science, 219, 983-985, 1983, cited by applicants) or Dvorak (U.S. Pat. No. 4,456,550, cited by applicants) or Criscuolo et al (J. Neurosurg. 69, 254-262, 1988, cited by applicants), any one of the aforementioned in view of Chen et al. (U.S. Pat. No. 5,073,492, cited by applicants).

The teachings of the primary references are discussed above. Each teaches isolation of VEGF from one or more animal species. However, none discloses bovine VEGF. '492 teaches the partial purification of bovine VEGF approximately the same size as guinea pig VPF (VEGF; Fig. 2, fraction III) which selectively stimulates endothelial cell growth (Fig. 5 and col. 4, line 6 to col. 5, line 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of any one of the primary references to purify bovine VEGF because '492 discloses that VEGF is present in bovine tissues. One would have

been motivated to make this modification in order to have bovine VEGF for use in veterinary applications for cattle. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 are provisionally rejected under the judicially created doctrine of double patenting over claims 45, 47, 51-53, 56, 57, 66-68, 84, 89 and 90 of copending Application No. 08/473276. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: both applications are directed to folliculo stellate-derived growth

factor in isolated form, and as this case is a continuation of 08/473276, the disclosures are identical.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-35 of copending Application No. 10/177485. Although the conflicting claims are not identical, they are not patentably distinct from each other because each is drawn to VEGF, including bovine VEGF, and compositions thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/177485 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-3, 11, 14-16, 18-25, 29-32, 34-37 and 40 are rejected under 35 U.S.C. 102(f) as there is evidence that applicants are not the inventors of the claimed subject matter. See US Patent Application number 10/177485. It is noted that the application has been published as US 2003 0108989.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. ***Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.***

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner